DETAILED ACTION

Applicants' arguments, filed December 5, 2008, have been fully considered but they are not deemed to be fully persuasive. The following rejections and/or objections constitute the complete set presently being applied to the instant application.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1, 3 – 15, 17 and 18 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 – 3, 5 – 11, 13 – 15, 17, 21, 23 and 36 – 38 of copending Application No. 10/507,368 in view of Yuasa et al. (Chem Pharm Bull 1994). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed August 5, 2008 and those set forth below.

Applicant does not argue the merits of the rejection but rather that this rejection is premature as US Patent Application 10/507368 has not issued or been allowed.

This is not found persuasive. This rejection will be maintained until the objection is overcome, such as by the filing of a terminal disclaimer. The claims of the co-pending case, in an amendment filed August 15, 2008, have been amended to recite a Markush group of porous particles materials of "dibasic calcium phosphate anhydrous, microcrystalline cellulose, pregelatinised starch, calcium silicate magnesium

aluminometasilicate and mixtures thereof". Yuasa et al. teaches that magnesium aluminometasilicate, calcium silicate or lactose can also be used as a porous material suitable for use in the preparation of oily medicines. Therefore, it would have been obvious to one of ordinary skill in the art to prepare a dosage form comprising lactose porous particles as recited in the instant claims, or calcium silicate and/or magnesium aluminometasilicate as Yuasa et al. teaches that these materials are functionally equivalent porous materials suitable for use in the preparation of dosage forms comprising oily materials.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. The series of rejections uner 35 USC 103(a) made over Morein et al. (WO 03/080029) and Yuasa et al. (Chem Pharm Bull 1994) are WITHDRAWN. Morein et al. is only available as prior art under 35 USC 102(e) and Applicants have submitted that at the time the claimed invention was made, both Morein et al. and PCT/SE2004/001017 [Examiner's Note: the instant application is the National Stage Entry of this PCT Application] were owned by the same applicant, Astrazeneca UK Limited (p 3 of the response). Therefore, Morein et al. (WO 03/088029) is disqualified as a reference under 35 USC 103(c) and thus the rejections are withdrawn.

7. Claims 1, 3 – 7, 9 – 13, 16 and 18 were rejected under 35 U.S.C. 103(a) as being unpatentable over Geller et al. (US 5,283,067) in view of Del Soldato et al. (US 5,861,426). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed August 5, 2008 and those set forth below.

Applicant traverses this rejection on the grounds that Geller discloses a dry formulation suitable for the preparation of a stable, aqueous suspension for parenteral administration which are prepared by a method which does not result in absorption or adsorption of the drug to the adjuvant because the drug is always in a solid form during the preparation. Therefore, Geller et al. does not teach a composition in which the drug is in melted form absorbed/adsorbed onto/into particles. Mannitol is used to obtain isotonic conditions and that there is not "functional" interaction between mannitol and diclofenac salt which would modify the properties of the active principle. Del Soldato et al. does not fulfill the deficiencies as Del Soldato et al. does not discloses a compound in melted form absorbed/adsorbed to a particle.

These arguments are not found to be persuasive. As discussed in the Office Action mailed on August 5, 2008, "melted form absorbed/adsorbed onto/into particles" has been treated as a product-by-process limitation. It is unclear what Applicant means by a "functional" relationship between the diclofenac salt and mannitol that would modify the properties of the active principle and how this functional relationship relates to the patentability of the instant claims. Modified physical properties or release characteristics of the active ingredient are not recited by any of the instant claims and the claims do not require a "functional relationship" between the various ingredients. Applicant has not presented any persuasive evidence that the products prepared by the cited prior art and the method of the instant claims are non-obvious variants of each other. Therefore, this rejection is MAINTAINED.

8. Claims 1, 3 – 7 and 9 – 18 were rejected under 35 U.S.C. 103(a) as being unpatentable over Geller et al. and Del Soldato et al. further in view of Patel et al. (US 6,248,363). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed August 5, 2008 and those set forth below.

Applicant traverses this rejection on the same grounds in regards to Geller et al. and Del Soldato et al. discussed in greater detail above. Patel et al. fails to disclose a composition having a drug in a melted form absorbed/adsorbed onto/into particles as it generally discloses pharmaceutical compositions comprising an active ingredient.

The arguments in regards to Geller et al. and Del Soldato et al. were not persuasive and therefore Patel et al. need not disclose having a drug in a melted form absorbed/adsorbed onto/into particles. Therefore this rejection is maintained.

9. Claims 1, 3 – 13, 16 and 18 were rejected under 35 U.S.C. 103(a) as being unpatentable over Geller et al. and Del Soldato et al. further in view of Miller et al. (US 5,763,452) and Nokhodchi et al. (Eur J Pharm Biopharm 2002).

Applicant traverses this rejection on the same grounds in regards to Geller et al. and Del Soldato et al. discussed in greater detail above. Miller et al. and Nokhodchi et al. fail to cure the deficiencies of Geller et al. and Del Soldato et al. as they do not disclose a composition having a drug in a melted form absorbed/adsorbed onto/into particles.

The arguments in regards to Geller et al. and Del Soldato et al. were not persuasive and therefore Miller et al. and Nokhodchi et al. need not disclose having a

drug in a melted form absorbed/adsorbed onto/into particles. Therefore this rejection is maintained.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

NMW